```
        ┌─────────────┐
        │ LABORATORY  │
        │ PROCEDURES  │
        │ DEFINITION  │
        └─────────────┘
               │
               ▼
        ┌─────────────┐
        │  STUDY /    │
        │  PROTOCOL   │
        │ DEFINITION  │
        └─────────────┘
               │
               ▼
        ┌─────────────┐
        │ ACCESSIONING│
        │  SAMPLES    │
        └─────────────┘
               │
               ▼
        ┌─────────────┐
        │  WORKLIST   │
        │  CREATION   │
        └─────────────┘
               │
               ▼
        ┌─────────────┐
        │  CHECKLIST  │
        │  CREATION   │
        └─────────────┘
               │
               ▼
        ┌─────────────┐
        │  PERFORM    │
        │  PROCEDURE  │
        │  STEPS      │
        └─────────────┘
               │
               ▼
        ┌─────────────┐
        │  RECORD     │
        │  RESULTS    │
        └─────────────┘
               │
               ▼
        ┌─────────────┐
        │  REPORT     │
        │  RESULTS    │
        └─────────────┘
```
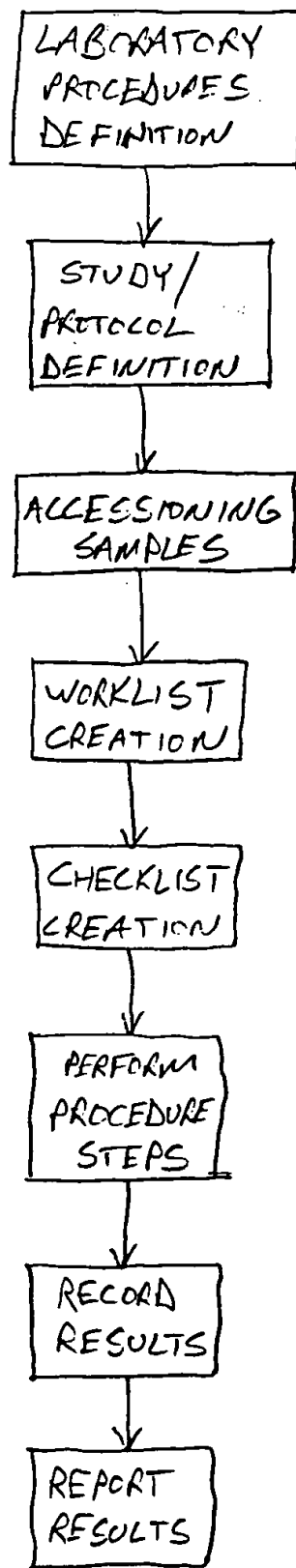
Fig 1

Study Setup

Clinical Study Definition

- Describes Sponsors & Investigators
- Declares Subject Attributes to Capture
- Associates Specific Lab Procedures with a Clinical Study
- Defines Genotype Results to Report

FIG. 2

Accessioning

Clinical Sample
Registration

– Provides Validation
Checks for Accession &
Tube ID's

– Accommodates Multiple
Sample Tubes

– Enforces Controlled
Subject Attribute Terms

– Supports Sample
Worklist Workflow

FIG. 3

Sample Tracking

- Supports Multiple Container Classes
- Allows User Defined Container Geometries & Templates
- Maintains Sample & Container Location
- Permits Flexible Sample Loading & Rearrangement
- Tracks and Maintains Container & Sample Ownership

FIG. 4

Sample Worklists

- Named Sample
  Collections

- Assignable to Lab
  Scientists

- Groups Samples for
  Common Lab Operations

  – Location

  – Check-in/Check-out

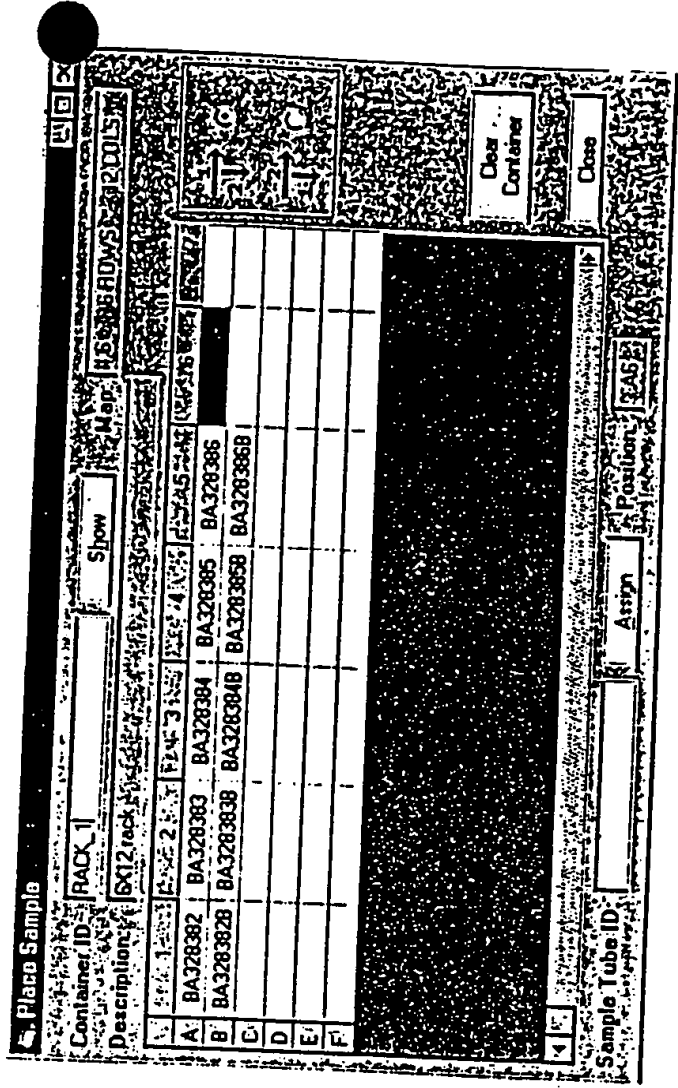 – Lab Procedures

FIG. 5

Electronic Procedure Checklists

Automates Laboratory
Process Tracking

- Supports Standard
  Operating Procedures

- Maintains Uniform
  Laboratory Processes

- Records Chain of
  Custody

- Tracks Repeat
  Operations

FIG. 6

Procedure

DNA Isolation, 3 mL whole blood, Purgene Kit

2D6 Allele "A" Identification

SpectroMax DNA quantitation

	Status	SOP Number	SOP Version
	APPROVED	GEN9709	C
	APPROVED	CYP2D6A	A
CYP2C9*3	APPROVED	MAX9802	A
CYP2C9*2 Ver.7	APPROVED	CYP2C9-3	A
CYP2C9*2 Ver.6	APPROVED	CYP2C9-2	A
CYP2C9*2	APPROVED	CYP2C9-2	A

Print   Save As

Procedure Name:

2D6 "Allele "A" Identification

Procedure Description:

Laboratory Protocol for Identification of CYP2D6 "A" Allele by RFLP-PCR

Gene:

Alleles:

SOP Number CYP2D6A

SOP Version A

Status APPROVED

New   Select

Modify   Cancel

Delete   Close

Created
DNALIMS   10/4/99 12:02

Modified
DNALIMS   10/5/99 10:59

FIG. 7

Procedure Steps

- A Single Step in a Lab Procedure
- Multiple Types:
  - Transfer
  - Dilution
  - Concentration Adjustment
  - Sample Preparation
- Highly Customizable
- Plug-in Architecture to Add New Types
- Interfaces to Automation

Procedure Steps

Procedure: DNA Isolation, 3 mL whole blood, Pugene Kit   Print

Step	Step Input Type	Functional Type	Level
Thaw frozen blood	CheckBox		Batch
Gently mix sample	CheckBox		Batch
Transfer 3 mL of blood to Lysis tube	Functional	Transfer	Batch
Add 9 mL of RBC lysis to RBC Lysis tube	Functional	Reagent Addition	Batch
Mix and incubate 10 minutes at room temperature	CheckBox		Batch
Centrifuge 10 minutes at 3000 RPM	Text		Batch
Pour off supernatant into biohazardous waste cont.	CheckBox		Batch
Resuspend cell pellet by vortexing	CheckBox		Batch
Add 3 mL of Cell Lysis Solution	Functional	Reagent Addition	Batch
Sample can be stored for 18 months at RT in Cell L...	Informational		Batch
STOP POINT...	Informational		

Steps: Add 9 mL of RBC lysis to RBC Lysis tube

Step Type   Step Level

- Informational / CheckBox   Sample
- Functional / Text   Batch

Reagent Addition

Volume	9000 uL
To final volume	FALSE
Reagent name	RBC Lysis S...
Reagent prefix	RL...
Volume optional	TRUE
Waive scanning	TRUE
Lock parameters	

Save Sequence   New   Save

Delete   Cancel

Modify   Close

Created   10/5/99 09:00   Modified   9/30/99 14:42

DNALIMS 14...   DNALIMS S...

FIG. 8

Genotype Results

- Accommodates Values for Multiple Genes, Alleles & Assays

- Provides Master Review by Accession Number

- Supports Acceptance & Final Approval by Study Director

- Imports Results Electronically or Manually

FIG. 9

Auditing

Track Changes in
Database
— Study
— Lab Procedures
— Sample
— Results
Flexible Audit Reporting
Chain of Custody by
Accession

Audit Report

Protocol Audit Trail

STUDY_PROTOCOL	AUDIT_ID	PROTOCOL_ID	SPONSOR_STI	SPONSOR_PROTOCOL_TITLE	PPGX_STUDY	PPGX_PROTOCOL_TITLE	CREATED_B
	895	01	AIA	Evaluation of	STUDY-1	X	DNAUMS
	896	01	AIA	Evaluation of	STUDY-1	X	DNAUMS
	001	01	AIA	Evaluation of	STUDY-1	X	DNAUMS
	051	01	AIA	Evaluation of	STUDY-1	Genomic DNA Isolation and	DNAUMS
	053	01	AIA	Evaluation of		Genomic DNA Isolation and	DNAUMS
	057	01	AIA	Evaluation of		Genomic DNA isolation and	DNAUMS
	060	01	PHD-001	Evaluation of		Genomic DNA Isolation and	DNAUMS
	064	01	PHD-001	Evaluation of		Genomic DNA Isolation and	DNAUMS
	071	01	PHD-001	Evaluation of		Genomic DNA Isolation and	DNAUMS
	098	01	PHD-001	Evaluation of		Genomic DNA Isolation and	DNAUMS
	1002	01	PHD-001	Evaluation of		Genomic DNA Isolation and	DNAUMS
	1003	01	PHD-000	evaluation of		Genomic DNA Isolation and	DNAUMS
		01	PHD-001	Evaluation of		Genomic DNA Isolation and	DNAUMS

Print   Close

FIG. 10

Reporting

- Multiple Report Types
  - Genotype Results
  - DNA Integrity
  - Purification Results
  - Sample Lists
  - Audit Trails
- Flexible Reporting Output Using Excel
- Customized Reporting Using 3rd Party Tools

DNA Purification Results

Study: Test
Study #: 999-xxx

Sponsor:
Representative:
Investigator(s):

Sample #	Storage #	µg/ml	Protocol	Start Vol.	DNA Vol.	Yield	A260	A230	A280	Subject Number	Initiate of Birth
	EA111111	0	Sample test	09/06:00	499	0	0	0	0	1:kal	5/31/65
	EA111112	0	Sample test	02/19:00	48	0	0	0	0	2 lhb	8/2/67
	EA111113	0	Sample test	09/06:00	248	0	0	0	0	3 lsc	5/22/65
	EA111114	0	Sample test	09/06:00	248	0	0	0	0	4 jmm	4/11/74
	EA111115	0	Sample test	09/06:00	248	0	0	0	0	5 lm	9/9/72
	EA111117	0	Sample test	09/06:00	248	0	0	0	0	1:kal	5/31/65
	EA111116	0	Sample test	09/06:00	98	0	0	0	0	2 lhb	8/2/67
	EA111118	0	Sample test	09/06:00	248	0	0	0	0	3 lsc	5/22/65
	EA111119	0	Sample test	09/06:00	582	0	0	0	0	4 jmm	4/11/74

FIG. 11